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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/373,230

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

01/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/373,230	OKMURA ET AL.	
	Examiner	Art Unit	
	DONG JIANG	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 18, 19, 24, 25 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED OFFICE ACTION

The request filed on 13 November 2008 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/373,230 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 13 November 2008 is acknowledged and entered. Following the amendment, the new claims 28 is added.

Applicant's amendment filed on 24 October 2008 is acknowledged and entered. Following the amendment, the new claims 18, 24 and 26 are amended.

Currently, claims 18, 19 and 24-28 are pending and under consideration.

Withdrawal of Objections and Rejections:

The new matter rejection of claims 18, 19, 26 and 27 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's amendment and argument.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite for the recitation "which can be obtained by recombinant DNA technology *based on the amino acid sequence of SEQ ID NO:2*" because it is unclear how it is based on the amino acid sequence of SEQ ID NO:2, i.e., how the sequence of SEQ ID NO:2 is modified, how the sequence of the claimed protein is identified, and/or what is structural identity of the claimed protein. The metes and bounds of the claim, therefore, cannot be determined as

Art Unit: 1646

the recombinant DNA technology does not define the sequence structure of the protein. Claim 28 is similarly indefinite.

The remaining claim is included in this rejection because it is dependent from the specifically mentioned claim without resolving the indefiniteness issue belonging thereto.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18, 19, 24 and 25 remain rejected, and the new claim 28 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention., for the reasons of record set forth in the previous Office Actions mailed on 8/8/07, 2/21/08, and 8/14/08, and for the reasons below.

Applicants argument filed on 24 October 2008 has been fully considered, but is not deemed persuasive for the reasons below.

At page 7 of the response, the applicant argues that claim 24 has been amended to further define the protein as one "which can be obtained by recombinant DNA technology based on the amino acid sequence of SEQ ID NO:2"; that claims 18 and 24 define the subject matter for which the specification provides adequate written description; and that the specification substantially discloses the methods for obtaining the polypeptide having the amino acid sequence of SEQ ID NO:2 and the variants thereof (Examples 1 and 2) in such a way as to reasonably convey to one of skill in the art that the applicants, at the time the application was filed, had possession of the claimed invention, when the state of the recombinant DNA technology is taken into account. This argument is not persuasive because the issue is not about the recombinant DNA technology, rather, the issue is that the claimed protein can be *anything* (such as a *functional equivalent* with no sequence similarity to SEQ ID NO:2) when made "based on the amino acid sequence of SEQ ID NO:2" (claims 24 and 28, for example), or with

“one or more amino acid in SEQ ID NO:2 replaced” (claim 18, for example), since no limitation defines the sequence identity of the encompassed genus of the claimed protein. With respect to the recombinant DNA technology, while allowing one skilled in the art to make variants of a polypeptide, does not define the structure of the genus of the protein. Therefore, with the exception of SEQ ID NO:2, a skilled artisan cannot envision the detailed chemical structure of the encompassed variants, and therefore conception is not achieved regardless of the complexity or simplicity of the method of making a peptide or chemical molecule. Accordingly, the specification does not provide adequate written description of the claimed genus.

At pages 8-9 of the response, the applicant presents argument regarding claim 26, such as that at least with regard to "one or two" amino acid modifications recited in claim 26, SEQ ID NO:2 has 157 amino acid residues, thus, a variant of SEQ ID NO:2 that only has a one or two amino acid residue modification is at least 98.7% identical in sequence to SEQ ID NO:2, and that this situation is analogous to Example 14 (Product by Function) in the USPTO's "Synopsis of Application of Written Description Guidelines". This argument is not persuasive because claim 26 is not included in the instant rejection. Further, the rejected claims 18, 19, 24, 25 and 28 do not only read on at least 98.7% variants of SEQ ID NO:2, and they encompass a broad genus including functional equivalent with no sequence similarity to SEQ ID NO:2.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Conclusion:

Claims 26 and 27 are allowable.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
1/18/09